REMARKS

1. Status of the Claims

Claims 1-5, 7-13, 39, and 41-43 were pending at the issuance of the Office Action mailed December 2, 2005. Claims 1, 7, 8, and 42 have been amended. New claims 49-54 have been added. Claim 13 has been canceled.

The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below. No new matter has been added as a result of the above-described amendments. The amendments set forth herein are submitted to expedite prosecution of the pending claims to allowance, and are not intended to indicate that Applicants have acquiesced to any of the assertions in the Office Action or positions taken therein. Applicants make these amendments without prejudice to their right to submit in a continuation application claims having a scope similar to the claims as filed.

2. Claim Objections

Claims 5, 7, 13, 42, and 43 are objected to as being in improper form. The claims have been amended and new claims 49-54 have been added to overcome these objections.

3. Rejection of claims 1-5, 7-13, and 39-43 under 35 U.S.C. § 101

The Office Action maintains the rejection of claims 1-5, 7-13, and 39-43 under 35 U.S.C. § 101 as being directed to an invention having no assertion of utility. Specifically, the Action states that the as-filed specification does not describe a specific and substantial utility for any of the claimed sequences. The Action, however, acknowledges that the as-filed specification does describe both a specific and credible utility for the claimed sequences.

MPEP 2107.01 indicates that deficiencies under 35 USC §101 arise in one of two forms: the first involves situations where applicant fails to identify ***any*** specific and substantial utility for the invention or fails to disclose enough information about the invention to make its usefulness immediately apparent to those of skill in the art; the second involves rare situations where the asserted specific and substantial utility is not credible. Applicants respectfully submit that the present case is not analogous to either of these situations.

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Regarding the first situation, Applicants have asserted a credible, specific and substantial use for the FGF-like polypeptide of the invention. Specifically, the specification provides ample evidence that the FGF-like polypeptide of the invention is a member of the FGF family (see for example Figure 3); the specification provides evidence that the FGF-like polypeptide of the invention is primarily expressed in the liver (page 4-5 and Figure 4); the specification indicates that overexpression of the FGF-like polypeptide of the invention in mice causes an identifiable phenotype; and, consistent with the phenotype of the transgenic mice, the specification specifically asserts that the FGF-like polypeptide of the invention may also be useful as growth or fat deposition inhibitors, in the treatment of excessive growth (for example, acromegaly), premature maturation, obesity or diabetes (page 5). Those of skill in the art would readily recognize at the time of filing that the transgenic mouse phenotype caused by overexpression of the FGF-like polypeptide of the invention, together with the expression pattern of the FGF-like polypeptide, correlated with the asserted utility.

Applicants note that the Action acknowledges on page 10 that the claimed FGF-like polypeptide is "likely to have a credible, specific and substantial practical use." However, the Action asserts that the specification does not disclose the use. Rather, the Action asserts that the "specification provides no more than suggestions for various avenues of experimental investigation to determine what biological or pharmacological activities of the FGF-like polypeptide might have."

The standard for meeting the utility requirement is set forth in MPEP 2107.02(I), which states that applicant only needs to make *one* credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. §101 and 35 U.S.C. §112 (emphasis added). Furthermore, a properly claimed invention only needs to meet *one* stated objective to show utility under 35 U.S.C. §101 (emphasis added). *In re Gottlieb*, 328 F.2d 1016, 1019, 140 USPQ 665, 668 (CCPA 1976). Thus, it does not matter how many potential utilities an applicant lists in an application, so long as *one* is found credible. Therefore, since the specification provides an assertion of utility that is supported by experimental evidence, Applicants submit that the utility requirements are satisfied, and respectfully request that this ground of rejection be withdrawn.

The Action asserts that the present case is "directly analogous" to *Brenner v. Manson,* 148 U.S.P.Q. 689 (Sup. Ct, 1966) and *In re Kirk*, 153 U.S.P.Q. 48 (CCPA 1967). In *Brenner*, the

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applicant claimed a process for making a compound that was structurally related to a known steroid having tumor-inhibiting effects. The Patent Office rejected the application based on the applicant's failure to disclose any utility for the compound produced by the claimed process. The applicant argued that the compound had a utility by virtue of its relationship to the known steroid. The Court dismissed the applicant's argument, because the applicant's specification failed to show that the compound had the same activity as the known compound, and, in addition, the specification did not disclose a sufficient likelihood that the compound should have similar tumor-inhibiting effects as the known steroid. The applicant also argued that the claimed process was useful because it worked to produce an intended product, and because the compound belonged to a class of compounds that were under scientific investigation. The Court again rejected the applicant's arguments, stating that processes should be developed to a point where "specific benefit exists in currently available form" to satisfy the utility requirement, and that "a patent is not a...reward for the search, but compensation for its successful conclusion."

The Court in *Brenner* also noted that granting a patent to the applicant for the process claims would be against public policy. Specifically, the Court noted that the ability of a patentee to enforce patents covering processes that generate compounds with unknown uses would inhibit others from searching for uses of those compounds. Such patents to processes that make compounds without a known activity would create a bottleneck to research, controlled by the patentee. Also, such process patents could cover future discovered compounds that could be made by the process, thereby hindering others from searching for uses of compounds that would be covered by the patents. The instant case, in contrast to *Brenner*, does not offend public policy, because the claims are to a distinct member of a known family of genes. Claims relating to the FGF-like polypeptides of the invention would not hinder research of other FGF family members, nor would the claims broadly prevent anyone from discovering other FGF family members.

In *Kirk*, the applicant claimed novel compounds, but failed to disclose any particular use for the compounds, and merely indicated that the compounds had "useful biological properties." The Court found that the specification did not provide any "specific allegation of utility for any compound within the scope of the claims." The applicant argued that those of skill in the art "would be able to determine the biological uses of the claimed compounds by routine tests." The Court held

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that a general statement of utility does not comply with the utility requirement. The applicant also argued that the claimed compounds were useful as intermediates in the formation of known steroids. As in *Brenner*, the Court held that the potential use of a compound in experimental research was not sufficient to satisfy the utility requirement.

The Action asserts that the Applicants, similar to the situation in *Brenner* and *Kirk*, are relying on the relationship of the FGF-like polypeptide of the invention to other known FGF proteins, without experimental evidence to show that the FGF-like polypeptide has any activity. In contrast to *Brenner* and *Kirk*, however, Applicants are not relying merely on structural similarity to a known class of compounds as proof of a utility for the claimed FGF-like polypeptides of the invention. Rather, Applicants point out that the specification discusses ***actual*** experimental evidence from transgenic mice (page 4) that demonstrate a specific, credible, and substantial utility for the FGF-like polypeptides of the invention, unlike the case in *Brenner* or *Kirk*, neither of which provided ***any*** evidence of utility. The specification demonstrates that overexpressing the FGF-like polypeptide of the invention causes a phenotype in the transgenic mice, including reduced body weight. Those of skill in the art recognize that a phenotype of a transgenic mouse can be attributed to the gene that is overexpressed in the mice. Thus, those of skill in the art would recognize that the FGF-like polypeptide of the invention has some utility in affecting the weight of an animal. As discussed on page 5, the specification clearly asserts that the FGF-like polypeptides of the invention may be useful as growth or fat deposition inhibitors, and in the treatment of excessive growth (for example, acromegaly), premature maturation, obesity or diabetes. Applicants respectfully submit that those of skill in the art would readily connect the experimental data described on page 4 of the specification with this particular asserted utility.

The Action also asserts that the instant specification, similar to the situation in *Brenner* and *Kirk*, "provides no more than suggestions for various avenues of experimental investigation to determine what biological or pharmacological activities the FGF-like polypeptide might have." Applicants, however, respectfully submit that the phenotype of transgenic mice, described in the specification and discussed above, does not merely invite further experimentation as in *Brenner* and *Kirk*, but provided evidence at the time of filing that the FGF-like polypeptide of the invention had a utility. The instant case is distinguished from *Brenner* and *Kirk* because neither *Brenner* nor *Kirk*

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provided any suggestion of a utility for the compounds, whereas Applicants have demonstrated that the FGF-like polypeptide of the invention has a particular expression pattern in the body and has a phenotypic effect when overexpressed in mice. Thus, unlike *Brenner* and *Kirk*, the instant specification does not leave those of skill in the art completely in the dark regarding a utility for the claimed invention, but provides evidence of a biological utility.

In view of the above discussion, Applicants submit that the utility requirements are satisfied, and respectfully request that this ground of rejection be withdrawn.

4. Rejection of claims under 35 U.S.C. § 112

Claims 1-5, 7-13, and 41-43 are rejected under 35 USC §112 first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Action indicates that the objection would be overcome by combining claim 1(d) parts (3) and (4) with the rest of claim 1(d). The claim has been amended, as suggested, thereby obviating this rejection.

Claims 7 and 12 are rejected under 35 USC §112, second paragraph as being indefinite. The claims have been amended to overcome this rejection.

5. Rejection of claims under 35 U.S.C. § 102

Claims 1, 2, 4, 8, 9, 11, and 39 are rejected under 35 USC §102 as being anticipated by GenBank Acc. No. AQ175436.

Claims 1, 2, 4, 8, 9, 11, and 39 are rejected under 35 USC §102 as being anticipated by GenBank Acc. No. AV050323.

Claims 1-5, 7-11, 13, 39 and 41-43 are rejected under 35 USC §102 as being anticipated by US 6,639,063.

The Action asserts that these references anticipate the instant claims as evidence by Kennel (Progr. Nucl. Acid Res. Mol. Biol. 11:259-301, 1971).

The Action relies on a generalized statement in Kennel, which states that "depending on the G+C content (21a), the stability of a complementary duplex of 25-50 nucleotides approaches that of

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any much longer complex." However, Kennel did not provide any experiment, but merely pointed to cited references to support its assertion. The reference #21(a) cited in Kennel was published by Niyogi ("Niyogi"). Neither Kennel nor Niyogi stand for the proposition that the stability of a complementary duplex of 25-50 nucleotides approaches that of any much longer complex under ***any particular*** hybridization conditions.

The Niyogi reference does not describe experiments testing the minimum number of nucleotides necessary to survive stringent hybridization conditions. In fact, the experiments merely determined the minimum number required to from a duplex under the optimum condition. (see page 1576, right col., 3rd para). The annealing was allowed to occur in the presence of 5X SSC, and the filter was washed in 5X SSC. Niyogi does not teach an annealing condition with low salt concentration at high temperature as in claim 1, nor does Niyogi teach an annealing condition with 50% formamide as in claim 1(it is known in the art that formamide greatly increase stringency). Finally, Niyogi does not teach a washing condition in 0.2X SSC as in claim 1. Thus, Niyogi does not teach nucleotide hybridization under stringent conditions such as provided in claim 1.

It is known by one skilled in the art, and further taught by Niyogi, that a longer sequence is needed under more stringent conditions, such as lower ionic strength and lower GC content (see Discussion in Niyogi). Additionally, Niyogi recognizes that a shorter length oligonucleotide requires lower temperature to form a stable complex, and complex formed by a longer oligonucleotide can survive higher temperature (see Niyogi p1579, left col, second full para). Thus, Niyogi does not teach that 20-50 nucleotides are all that is needed to form a stable complex under ***any*** hybridization conditions. Moreover, Niyogi does not teach, and one skilled in the art would not know, exactly under what GC content will 20-50 nucleotides be sufficient to form a stable complex. Thus, Applicants respectfully submit that Kennel, which relied on Niyogi, does not stand for the proposition that the stability of a complementary duplex of 25-50 nucleotides approaches that of any much longer complex under any hybridization condition, such as the high stringent conditions of claim 1. Consequently, Applicants submit that the cited references cannot anticipate the instant claims, and respectfully request these grounds of rejection be withdrawn.

CONCLUSIONS

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Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner Priebe believes it to be helpful, he is invited to contact the undersigned representative by telephone at 312-913-0001.

Respectfully submitted,
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